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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

ALLERGAN USA, INC., and ALLERGAN INDUSTRIE, SAS,

Plaintiffs,

v.

MEDICIS AESTHETICS, INC., MEDICIS PHARMACEUTICAL CORP., VALEANT PHARMACEUTICALS NORTH AMERICA LLC, VALEANT PHARMACEUTICALS INTERNATIONAL, VALEANT PHARMACEUTICALS INTERNATIONAL, INC., AND GALDERMA LABORATORIES, L.P.

Defendants.

Case No. SACV13-01436 AG (JPRx)

PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION FOR PARTIAL SUMMARY JUDGMENT OF NO INVALIDITY FROM PRIOR USE

Judge: Hon. Andrew J. Guilford
Hearing: June 1, 2015 at 10:00 a.m.
Ctrm: 10D

Discovery cutoff date: May 15, 2015
Pretrial conference date: July 20, 2015

Trial date: August 4, 2015

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I. INTRODUCTION

Defendants first raised their prior use defense on the February 17, 2015—the last date possible and the deadline for their final contentions and opening invalidity expert reports. But in their contentions and expert report, Defendants failed to identify any evidence that establishes an invalidating prior use. The only "evidence" cited turned out to be "facts" told to the expert by Defendants' lawyers and a 2009 article that does not prove that doctors were pre-mixing lidocaine into HA fillers before 2008 in the United States. Allergan thus moved for summary judgment on this new defense based on this total lack of evidence.

Recognizing that the prior use evidence included in their invalidity contentions and invalidity expert report was legally insufficient, Defendants' opposition tries to add a plethora of new documents and testimony to avoid summary judgment. That violates the Standing Patent Rules and Federal Rules, which require Defendants to identify all evidence of prior use in their invalidity contentions and expert reports, which they didn't do. Permitting Defendants to add this new evidence at this late stage would severely prejudice Allergan because, had Allergan known Defendants would use this evidence, its motion would have established that none of it is prior art because it all post-dates the conception and reduction to practice of the invention in 2005. Therefore, as explained further in Allergan's co-pending motion to strike, Defendants should be precluded from relying on any of this evidence.

Even if the Court were to consider the newly raised evidence, Allergan is still entitled to summary judgment. Neither Dr. Lebreton, the inventor, nor Allergan's *Markman* brief provided evidence that there was a relevant ***prior*** use (*i.e.*, that physicians were mixing HA-BDDE fillers with lidocaine in the United States before August 2008). In fact, the inventor's best recollection was that physicians began mixing only ***after*** his invention came to market. Meanwhile, Defendants' other evidence is inadequate because it does not relate to any prior use by Dr. Nestor (who

is the only doctor they have specifically identified as allegedly mixing HA-BDDE and lidocaine), does not relate to a use in the United States, does not relate to the claimed HA-BDDE filler, or occurred after Allergan's 2005 invention date. Defendants are thus left with only oral testimony from Dr. Nestor and his assistant, and that is legally inadequate under the Federal Circuit precedent discussed in Allergan's motion and ignored by Defendants' opposition. Specifically, the Federal Circuit has rejected Defendants' argument that *Thomson* somehow excuses them from providing corroboration, and it has held that the "rule of reason" never comes into play where, as here, a defendant presents no corroboration at all. On this record, the Court should grant Allergan's motion for partial summary judgment.

II. ARGUMENT

A. The Court Should Decide this Motion Based Only the Evidence Disclosed by Defendants by the Time It Was Filed.

Allergan's summary judgment motion showed that Defendants' contentions and expert reports are devoid of the evidence needed to establish a prior use under Section 102, which requires "the invention was known or used by others in this country" before the patent holder's invention date or was "in public use or on sale in this country" more than a year before the patent's filing date. *See* 35 U.S.C. § 102(a), (b). Defendants' main response is to identify new evidence that was not cited in their invalidity contentions or expert report and argue that the new evidence precludes summary judgment. This is not permitted. As explained in Allergan's co-pending motion to strike, the Standing Patent Rules required Defendants to be specific in their invalidity contentions about "who" had made the allegedly invalidating prior uses, "when" they occurred, and what evidence supported those allegations. *See* S.P.R. 2.5.1 & 4.2. Defendants failed to do so. The prior use defense was not in their initial April 2014 contentions or their October 2014 supplemental contentions; instead, it first appeared on the last day possible in their February 17, 2015 final invalidity contentions. Even then, the final contentions

didn't cite ***any*** of the evidence upon which Defendants now rely:

Alleged "Evidence" in Defendants' Opposition (Exs. to Doc. No. 132)	Cited In Invalidity Contentions?	Cited In Invalidity Report?
Lebreton Testimony (Ex. C)	No	No
Lango Testimony (Ex. V)	No	No
2006 Q-Med Document (Ex. O)	No	No
Allergan *Markman* Brief	No	No
Oct. 2007 Agenda (Ex. F)	No	No
Nov. 2008 Presentation (Ex. G)	No	No
2009 Juvederm email (Ex. H)	No	No
Lupo Testimony (Ex. N)	No	No
2007 paper on Radiesse (Ex. I)	No	No
2009 Beasley article (Ex. Q)	No	Yes
Nestor "rebuttal" report (Ex. S)	No	No
2009 Internet posting	No	No
Santos declaration (Ex. T)	No	No

Defendants' attempt to back-fill in their opposition brief flouts the Standing Patent Rules. This Court adopted those Rules to "reduce transaction costs and increase procedural predictability," S.P.R. at 1, and "to proceed orderly and promptly to trial." (Doc. No. 105 at 3.) As a result, both these Rules and the Federal Rules require that Defendants put all their cards on the table and specifically identify the evidence on which they want to rely. That way, Allergan could tailor its summary judgment strategy accordingly. But Defendants never did this—at most, their claim charts vaguely asserted without explanation that practitioners were premixing before August 2008. (Doc. No. 123-1 at 3-5.) Allergan relied on Defendants' (lack of) disclosure in crafting this motion, choosing to focus on the lack of corroboration. If Allergan had known Defendants would be relying on all this newly cited evidence to support invalidity, it would have taken a different tack

with this motion and challenged other deficiencies in Defendants' proof. (*See, e.g.*, *id.* at 8 n.1.) For example, much of the "evidence" Defendants now cite is not even prior art because Allergan conceived the invention and reduced it to practice in 2005, (*e.g.*, Countryman Decl., Exs. 10 & 11), well before the earliest date when Dr. Lupo or anyone else is alleged to have begun pre-mixing HA-BDDE dermal fillers with lidocaine in the United States. Indeed, Allergan provided an interrogatory answer on January 6, 2014 that identified 2005 as Dr. Lebreton's reduction to practice date. (Ex. 11 at 12-13.) As another example, Allergan could have challenged that any alleged pre-mixing does not even result in the claimed composition; or that Defendants have not presented any proof on limitations of some claims (*e.g.*, maintenance of extrusion force for 9 months and meeting the requirement for sterility). (*See, e.g.*, Doc. No. 84-1 & 84-2.) But Allergan didn't do any of this because it relied on the procedure for disclosing evidence set by the Standing Patent Rules and saw that Defendants had not disclosed legally sufficient evidence of prior use before the August 2008 filing date under those Rules.

Defendants regrettably respond by blaming Allergan for their own failings, asserting that they were relying on an alleged "admission" in Allergan's June 2014 *Markman* brief. (Doc. No. 130 at 6-8, 16.) But this can't be true. Defendants supplemented their contentions after the *Markman* order in October 2014 to add a different defense (indefiniteness) but did not add a prior use defense or incorporate the so-called admission from Allergan's brief. And they inexplicably waited for months to serve any discovery on their prior use defense. When Defendants finally did serve Requests for Admission in January 2015, Allergan investigated and promptly denied any invalidating prior use. And, as discussed below, when Defendants asked the inventor, Dr. Lebreton, at his January 2015 deposition about when doctors began premixing HA-BDDE dermal fillers with lidocaine, he said that he didn't know, but his best guess was that it was ***after*** his invention had already come to market. (Ex. 12 at 52:24-54:4.) So Defendants' problem here was not

detrimental reliance; it was that they sat on their hands and waited until after the February 17, 2015 deadline for final invalidity contentions had passed to try in earnest to collect evidence on the defense. If Defendants really thought that Allergan's June 2014 brief was the smoking gun, they would have supplemented their contentions immediately and taken discovery. They never explain why they failed to do so. The Court should thus enforce the Standing Patent Rules as written and decide this motion based only on the evidence that Defendants timely disclosed.

B. Defendants Have Presented No Timely Evidence of Public Use.

1. Defendants Have Not Corroborated Dr. Nestor's Testimony.

When the analysis is limited to the proper record, Defendants have pointed to no legally sufficient evidence of an invalidating prior public use in the United States before August 2008. As an initial matter, the table above shows that Defendants did not disclose ***any*** evidence of a pre-August 2008 use with their invalidity contentions, so summary judgment is appropriate on that basis alone. That aside, even their late disclosure of Dr. Nestor's testimony about his own alleged prior use is insufficient because it is not adequately corroborated.

Defendants first argue (at 12-13) that Dr. Nestor's testimony does not need corroboration because he is an "uninterested" witness, citing *Thomson S.A. v. Quixote Corp.*, 166 F.3d 1172 (Fed. Cir. 1999). But subsequent Federal Circuit authority has clarified that *Thomson* does not stand for the proposition that an uninterested witness's testimony alone can invalidate a patent. Instead, *Finnigan Corp. v. Int'l Trade Comm'n*, 180 F.3d 1354 (Fed. Cir. 1999), held that ***all*** allegedly invalidating testimony requires corroboration and distinguished *Thomson* as a situation where documentary corroboration ***was*** presented:

> *Thomson* did not involve uncorroborated testimony of a single witness. Indeed, the district court in that case "noted that the evidence supporting the anticipation finding [included] … an expert's exhibits; and certain . . . documents that the expert had reviewed." Therefore, ***the facts of Thomson did not present the question of the necessity of corroboration vel non, but rather the sufficiency of the corroborating evidence, a distinct inquiry*** involving an assessment of the totality of the circumstances, including consideration of "the interest of the corroborating witness in the subject

> matter of the suit." . . . .
>
> [*Thomson*] do[es] not stand for the proposition that only an interested witness's testimony requires corroboration. In any event, ***corroboration is required of any witness whose testimony alone is asserted to invalidate a patent, regardless of his or her level of interest***.

Id. at 1368-69 (emphases added). So Defendants cannot evade the corroboration requirement by portraying Dr. Nestor as "uninterested," and anyway, he is interested because he is their paid expert.

Defendants are similarly incorrect when they try (at 13-14) to invoke the "rule of reason," which requires a court to look at the totality of the evidence when assessing the ***sufficiency*** of corroboration. Here, Defendants have not identified any corroborating evidence at all, so the rule of reason analysis does not come into play. *See Finnegan*, 180 F.3d at 1369-70 & n. 11 (explaining the "rule of reason" analysis is a "different question" from whether testimony alone can invalidate a patent). Defendants' cited cases (at 13-15) under the rule of reason all involve situations where corroborating evidence other than testimony was provided. *See, e.g.*, *Loral Fairchild v. Matsushita Elec. Indus. Co.*, 266 F.3d 1358, 1364-65 (Fed. Cir. 2001) (holding that "documentary evidence to corroborate test results" was not required where other documents showing the delivery date of the allegedly invalidating masks and a written proposal describing their structure had already been provided); *Lacotte v. Thomas*, 758 F.2d 611 (Fed. Cir. 1985) (holding that forms showing an inventor obtained supplies needed to practice the invention were sufficient corroboration); *Zenith Elecs. Corp. v. PDI Comm'n Sys.*, 522 F.3d 1348, 1357-58 (Fed. Cir. 2008) (noting that "a product literature sheet" that included a corporate address from before the critical date corroborated testimony of prior public use).

So the applicable law is not what Defendants cite, it is the cases discussed at pp. 8-12 of Allergan's opening brief, none of which Defendants address. Under that law, none of the evidence upon which Defendants rely actually corroborates Dr. Nestor's testimony. Defendants' proffered declaration from his assistant, Ms.

Santos, is insufficient because it is simply more oral testimony, and that doesn't count as corroboration. As explained in Allergan's opening brief, *The Barbed Wire* case rejected the testimony of 24 witnesses, while *Juicy Whip* rejected the testimony of 6. (Doc. No. 123-1 at 8-9, 11.) Defendants' opposition ignores that law. And, notably, Defendants identify no written patient record or other contemporaneous document to support the testimony of Dr. Nestor and Ms. Santos, even though Allergan's opening brief specifically flagged this deficiency.

Likewise, Dr. Lebreton's testimony and Allergan's *Markman* brief are not corroborating evidence. As discussed further in the next section, these items do not actually say that premixing occurred in the United States before August 2008, which is what Defendants would need to prove, at minimum, to invalidate Allergan's patents based on prior use. That aside, neither those things nor any of the other alleged "evidence" corroborate that ***Dr. Nestor*** himself made a prior public use of the claimed invention before August 2008. That other evidence—namely, Dr. Lupo's testimony, Allergan's documents, and Q-Med's internal practice outside the United States—says nothing about what Dr. Nestor was doing before August 2008. And, of course, it was all from after 2005, by which point Dr. Lebreton had already conceived and reduced the invention to practice. (See, e.g., Ex. 10 & 11.)

Defendants' citation to journal articles (at 15-16) is equally unavailing. One is from 2009, and it thus does nothing to prove what was occurring in the United States by August 2008. The others—a pair of articles by Busso et al.—are irrelevant because they dealt with mixing the ***non-HA*** filler Radiesse with lidocaine. (Exs. I & J.) They do not say anything about the claimed composition, which is an HA-BDDE dermal filler that contains lidocaine. Defendants complain (at 16) that "Allergan offers no evidence why physicians would have been premixing lidocaine into Radiesse (a non-HA filler) but not into HA fillers," but this gets things exactly backwards. ***Defendants*** have the burden to prove prior use of an HA-BDDE filler that includes lidocaine and meets all the other claim limitations by clear and

convincing evidence. *See Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238 (2011). Their speculation that physicians must have been mixing lidocaine with HA-BDDE fillers to make the claimed compositions because they were mixing lidocaine with the non-HA Radiesse product does not meet that burden. In fact, the need to swish with Radiesse with lidocaine was more acute because, as one of the Busso papers explains, Radiesse was extraordinarily painful to inject, and it was such a stiff gel that mixing with lidocaine helped to change its rheological properties to make it more spreadable after injection into a patient. (Doc. No. 132, Ex. I.)

2. Allergan Did Not Admit an Invalidating Prior Use.

Defendants also try to circumvent the corroboration requirement by pointing to evidence that they say "needs no corroboration," like some untimely-identified documents, Allergan's *Markman* brief, and Dr. Lebreton's testimony. (Doc. No. 130 at 9-12.) But none of this material supports their position.

To begin, Dr. Lebreton did not admit that any physician (or anyone else) was mixing HA-BDDE fillers with lidocaine before August 2008. In the first part of his cited testimony, Dr. Lebreton testified about ***different*** prior art techniques, such as "pretreatment" of a patient by applying an anesthetic cream or by first injecting lidocaine and then separately injecting an HA filler (as opposed to mixing them together and injecting the mixture):

> Q. Dr. Lebreton, would you agree that at the time that you began working on HA dermal filler compositions with lidocaine, that physicians were commonly treating patients with lidocaine when providing dermal fillers?
>
> THE WITNESS: So lidocaine or anesthesia is a concern because of patient getting some pain because of the needle, because of the treatment. So it was commonly used as a ***pretreatment***. I mean, anesthesia lidocaine, another form of ***creams***, you know, or another form of liquid injections. So yes, I mean, anesthesia was commonly used.

(Doc. No. 130 at 4, *citing* Ex. C at 46:23-48:3 (objection omitted) (emphases added).) Defendants then cite a passage where they followed up with a question that was not specific in time (and thus not directed to pre-filing practices). (*Id.*) Dr. Lebreton responded that there "are" (present tense) several techniques for using

lidocaine, but he did not say anything about the practice before August 2008:

> Q. And when physicians used lidocaine in their own offices, did they do so in a variety of different ways?
>
> MS. FLANAGAN: Objection. Calls for speculation. Vague.
>
> Q. What I mean by that is, sometimes they premixed lidocaine on their own. Sometimes they used topical lidocaine. Sometimes they may have given a separate lidocaine injection. Are you familiar with these different types of practices?
>
> A. Yes. There ***are*** several techniques that could be done to achieve this kind of anesthesia treatment. Could be cream, again, could be injecting directly lidocaine into the area before the treatment, or it could be this kind of mixing HA with lido that we have seen also.

(*Id*.) What Defendants' opposition does not cite is a passage from Dr. Lebreton's testimony a few pages later, where he testified that he did not specifically recall when pre-mixing lidocaine and HA-BDDE fillers began, but that his best recollection was that it happened ***after*** Allergan's lidocaine-containing products were introduced:

> Q. Going back for one moment. Did you learn in 2004 that physicians were premixing lidocaine with [Allergan's predecessor] Corneal's dermal fillers?
>
> ***A. I cannot remember.***
>
> ***
>
> Q. When in particular did you come to understand that there was this practice of premixing?
>
> A. That's difficult. I cannot answer this. This -- you know, again, this is more than 14 years for me. This is a very dynamic market. I mean, you've got new techniques every other week. So my belief in that is also that this practice came also strongly or presently or ***after we did introduction of the Juvederm lidocaine product***.

(Ex. 12 at 52:24-54:4.) So Dr. Lebreton's best recollection was that pre-mixing occurred after his invention had already been developed and introduced into the European market, which would mean that it couldn't be prior art, as those products were introduced in 2008. *See, e.g.,* http://goo.gl/AbD5vg (last visited May 4, 2015).

Similarly, Defendants cannot reasonably claim reliance on Allergan's *Markman* brief. As described above, Defendants did not even add this prior use defense to their contentions until February 2015, more than a month after Dr.

Lebreton testified that he was not aware of any prior use and disagreed with the statements in the *Markman* brief. (Ex. 12 at 34:19-36:7, 52:24-54:4.) And when they added the allegation to the final contentions, Defendants did not cite to the *Markman* brief in support. Likewise, Defendants' expert did not cite to the *Markman* brief in support of his opinion about prior use, even though it was on his laundry list of materials considered. Instead, he says that he "has been told" that premixing had occurred. (Doc. No. 123-7 at ¶¶ 227, 229.)

Defendants' failure to rely on the *Markman* brief makes perfect sense—statements by Allergan's lawyers are not evidence. Defendants point to the following passage from the technology overview portion of the brief:

> Dr. Pierre Lebreton began working on these compositions in the mid-2000s. At that time, physicians were commonly treating patients with lidocaine either topically or by injection before injecting the HA filler. Alternatively, some physicians were mixing lidocaine into the HA filler immediately before injection.

(Doc. No. 61 at 4.) Allergan acknowledges that, at the time the *Markman* brief was written, its lawyers knew that pre-mixing had occurred before the August 2008 filing date but were on unclear when it started. But, after further investigation, it turns out that premixing did not start until long after Dr. Lebreton's invention in 2005. To the extent this statement by counsel is ambiguous regarding the timing of when pre-mixing started, it should not be held against Allergan. Allergan never sought to benefit from the statement—it was simply part of a background section intended to provide context for the Court. Moreover, there was no indication Defendants were relying on the statement, despite what they say now, because they didn't include the prior use defense in their contentions until the last day possible and, even then, they didn't cite to the *Markman* brief in support of their contentions.

In these circumstances, the Court should not to treat the passage in Allergan's *Markman* brief as any sort of judicial admission. *See, e.g.*, *Trans-Tec Asia v. M/V Harmony Container*, 435 F. Supp. 2d 1015, 1026 (C.D. Cal. 2005) (statement in a brief not a judicial admission where the party who made it had not tried to benefit

from it and the other party had not detrimentally relied on it). Indeed, the next sentences in Allergan's *Markman* brief highlight Dr. Lebreton's surprising discovery that lidocaine could be formulated into BDDE-crosslinked HA fillers without degrading the properties and long-term performance and describe him as "going against the conventional wisdom" in doing so. (Doc. No. 61 at 4.) To accept Defendants' arguments would be to say that Allergan's lawyers—when providing the context of Dr. Lebreton's invention—actually admitted that the inventions were anticipated. That would be a grossly unjust result. Defendants' cited cases (at 10-11) do not support such a result because they involved circumstances where the party had tried to benefit from its previous statement, had caused its opponent to detrimentally rely on the admission, and/or the party had the burden of proof and had effectively admitted it couldn't meet that burden. None of that is present here.

Nevertheless, even if the Court were to treat the statement as a judicial admission, it would not preclude summary judgment. The statement just refers generically to mixing "HA fillers" with lidocaine, without specifically mentioning the claimed HA-BDDE crosslinked dermal filler, much less Restylane, Perlane, or Juvederm. Moreover, this passage does not say that pre-mixing was occurring in the United States, as would be required to show it is prior art under 35 U.S.C. § 102, or that the physician mixing would result in the claimed compositions.

Finally, Defendants' reliance (at 9-10) on alleged admissions in two Allergan documents and by Allergan's expert Dr. Lupo is misplaced. None of this information was disclosed in Defendants' invalidity contentions, or, indeed, at any time before their opposition to this motion. As noted above, none of this information is actually prior art, because it all occurred well after Allergan's conception and reduction to practice, (*e.g.*, Exs. 11 & 12), and, had Defendants timely disclosed it, Allergan could have tailored its motion accordingly. This untimely information thus cannot preclude summary judgment given Allergan's reliance on Defendants' prior non-disclosure.

The bottom line is that Defendants have injected all this new evidence and these new alleged admissions now because of their failure to include sufficient evidence in either their final invalidity contentions or in Dr. Prestwich's validity report. Defendants' attempt to avoid summary judgment by citing this new material now violates the rules and is highly prejudicial to Allergan. The Court should not deny Allergan's motion based on this untimely material.

III. CONCLUSION

For the reasons above, the Court should grant partial summary judgment that Defendants' invalidity defenses based on the allegation that doctors pre-mixed prior HA-BDDE fillers with lidocaine before August 2008 fail as a matter of law.

Dated: May 4, 2015

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the above and foregoing document has been served on May 4, 2015 to all counsel of record who are deemed to have consented to electronic service via the Court's CM/ECF system per Civil Local Rule 5.4. Any other counsel of record will be served by electronic mail, facsimile and/or overnight delivery.

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